


PATENT COOPERATION TREATY
PCTINTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 041381CP	FOR FURTHER ACTION See Form PCT/IPEA/416																	
International application No. PCT/CN2004/001070	International filing date (day/month/year) 20. Sep. 2004 (20. 09. 2004)	Priority date (day/month/year) 19. Sep. 2003 (19. 09. 2003)																
International Patent Classification (IPC) or national classification and IPC C07H15/18, A61K31/70, A61K31/7028, A61K35/78, A61P3/00, A61P15/02, A61P15/08, A61P15/12, A61P19/10																		
Applicant Shanghai YAO GANG Biological Technology Co. Ltd. et al.																		
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <table border="0"><tr><td><input checked="" type="checkbox"/> Box No. I</td><td>Basis of the report</td></tr><tr><td><input type="checkbox"/> Box No. II</td><td>Priority</td></tr><tr><td><input type="checkbox"/> Box No. III</td><td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td></tr><tr><td><input type="checkbox"/> Box No. IV</td><td>Lack of unity of invention</td></tr><tr><td><input checked="" type="checkbox"/> Box No. V</td><td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td></tr><tr><td><input type="checkbox"/> Box No. VI</td><td>Certain documents cited</td></tr><tr><td><input type="checkbox"/> Box No. VII</td><td>Certain defects in the international application</td></tr><tr><td><input type="checkbox"/> Box No. VIII</td><td>Certain observations on the international application</td></tr></table>			<input checked="" type="checkbox"/> Box No. I	Basis of the report	<input type="checkbox"/> Box No. II	Priority	<input type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/> Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/> Box No. VI	Certain documents cited	<input type="checkbox"/> Box No. VII	Certain defects in the international application	<input type="checkbox"/> Box No. VIII	Certain observations on the international application
<input checked="" type="checkbox"/> Box No. I	Basis of the report																	
<input type="checkbox"/> Box No. II	Priority																	
<input type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability																	
<input type="checkbox"/> Box No. IV	Lack of unity of invention																	
<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement																	
<input type="checkbox"/> Box No. VI	Certain documents cited																	
<input type="checkbox"/> Box No. VII	Certain defects in the international application																	
<input type="checkbox"/> Box No. VIII	Certain observations on the international application																	
Date of submission of the demand 11. April. 2005 (11.04. 2005)	Date of completion of this report 09. Nov. 2005 (09. 11. 2005)																	
Name and mailing address of the IPEA/CN The State Intellectual Property Office, the P.R.China, 6 Xitucheng Rd., Jimen Bridge, Haidian District, Beijing, China 100088 Facsimile No. 86-10-62019451	Authorized officer  Telephone No. 86-10-62085625																	

BEST AVAILABLE COPY

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/CN2004/001070

Box No. I Basis of the report

1. With regard to the language, this report is based on:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rules 12.3(a) and 23.1(b))
- ☐ publication of the international application (Rule 12.4(a))
- ☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

- ☐ the international application as originally filed/furnished
- ☐ the description:
- pages _____ as originally filed/furnished
- pages * _____ received by this Authority on _____
- pages * _____ received by this Authority on _____
- ☐ the claims:
- pages _____ as originally filed/furnished
- pages * _____ as amended (together with any statement) under Article 19
- pages * _____ received by this Authority on _____
- pages * _____ received by this Authority on _____
- ☐ the drawings:
- pages _____ as originally filed/furnished
- pages * _____ received by this Authority on _____
- pages * _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/CN2004/001123

Box No. I Basis of the report

1. With regard to the language, this report is based on:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of:
 - ☐ international search (Rules 12.3(a) and 23.1(b))
 - ☐ publication of the international application (Rule 12.4(a))
 - ☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ the international application as originally filed/furnished
- ☐ the description:
 - pages _____ as originally filed/furnished
 - pages _____ received by this Authority on _____
 - pages _____ received by this Authority on _____
- ☐ the claims:
 - pages _____ as originally filed/furnished
 - pages _____ as amended (together with any statement) under Article 19
 - pages _____ received by this Authority on _____
 - pages _____ received by this Authority on _____
- ☐ the drawings:
 - pages _____ as originally filed/furnished
 - pages _____ received by this Authority on _____
 - pages _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/CN2004/001070

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement:

Novelty (N)	Claims 1-4	YES
	Claims	NO
Inventive step (IS)	Claims 1-4	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-4	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

1. Cited documents

D1: JP-A-2-36189

D2: WO-A1-9610408

D3: CN-A-1432383

D4: CN-A-1379036

D5: CN-A-1291613

D6: CN-A-1424318

D7: China Journal of Chinese Materia Medica, Vol.26, No.2, Feb., 2001, Xiao Y.Q et al, "Studies on Chemical Constituents from Root of *Saposhnikovia divaricata* (Turcz.) Schischk", p117-119

2. Novelty

2.1 The compound claimed by claim 1 is related to a glucoside from *Epimeredi indica*(L) *Rothmalex* of formula I, document D1-D2, D4-D6 disclosed similar glucoside. In particular, the compound detailed disclosed in document D1(cf. claim 1 and Compound of formula I), document D2(cf. specification, page 9, compound of formula Ia), document D4(cf. specification, page 5-6, compound No.5-7), document D5(cf. the compounds disclosed in the specification. page3), document D6(cf. specification, page 1) possess quite same main structure with those claimed by claim 1.

In the view of documents D1-D2 and D6, the compound claimed by claim 1 are in particular novel through the substituents of the phenyl radical of the formula, i.e. those substituents of the formulas of D1-D2 and D6 are selected from hydrogen, hydroxyl or glucoside, while those of claim 1 are further selected from methoxyl.

In the view of document D4, the compound claimed by claim 1 are in particular novel through the additional substituents bonded to the glucoside radical, i.e., one of the hydroxyl group of the glucoside radical in the formulas of D4 is substituted by a acetyl group, while that of claim 1 is unsubstituted.

In the view of document D5, the compound claimed by claim 1 are in particular novel through the alkylidene radical bonded to the glucoside radical, i.e., the alkylidene radical of the formulas of D5 is substituted by a ethoxyl group, while that of claim 1 is unsubstituted.

Further, document D3 and D7 did not disclose any detailed compound of formula I.

Thus, in the view of D1 to D7, the compounds claimed by claim 1 complies with the criterion of novelty according to the PCT 33(2).

2.2 Claims 2-3 relate to the composition or formulation containing the compound of claim 1, while there are no disclosing of same composition or formulation in document D1 to D7, thus, the composition or pharmaceuticals and preparation claimed by claim 2-3 complies with the criterion of novelty according to the PCT 33(2).

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of V:

2.3 Claims 4 relates to the preparation method of the pharmaceuticals containing the compound of claim 1, while there are no disclosing of same preparation methods in document D1 to D7, thus, the preparation method claimed by claim 4 complies with the criterion of novelty according to the PCT 33(2).

3. Inventive Step

3.1 claim 1 relate to a glucoside from *Epimeredi indica(L) Rothmalex* of formula I, which are used for the treatment of the disorders relating to estrogen or progestogen dysequilibrium.

Although the compounds disclosed in documents D1-D2, D4-D6 possess high similar stucture with that claimed by claim 1, the compounds disclosed in D1 are used for the treatment of diabetic disorders, the compounds disclosed in D2 are used as cardioactive agent, the compounds disclosed in D4 and D6 are used for the treatment of nerve cell(neurocyte) apoptosis, and there is no detailed disclosing about the medicinal use of compounds in D5. Although document D3 disclosed that the roots of *Epimeredi indica(L) Rothmalex* can be used for the treatment of the disorders relating to estrogen or progestogen dysequilibrium, but there is no disclosing of detailed compound of formula I. Neither detailed compound of formula I nor the same medicine use are disclosed in document D7.

Thus, in the view of D1 to D7, the compounds claimed by claim 1 complies with the criterion of inventive step according to the PCT 33(3).

3.2 As the compounds claimed by claim 1 complies with the criterion of inventive step, based on the same reason, the composition, formulation, and their praration method of the compounds claimed by claim 1 also complies with the criterion of inventive step according to the PCT 33(3).